Regulation of Manganese in the United States

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Manganese ores, alloys and chemicals have been processed in the United States for well over a hundred years. In the early years, there was little control of exposures to workers or emissions to the environment. That changed in the 1950's and 60's as companies adopted more modern processes, labor unions pushed for better working conditions while federal laws and regulations mandated minimal standards.

Over the next decades, the federal and state regulatory agencies grew rapidly. Using an array of regulations and permits, these agencies now control many aspects of mineral, material and chemical production and nearly all aspects of emission control and waste disposal. While not at the top of the list in terms of concern, manganese is now a heavily regulated substance in the United States.

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There are four areas of concern that relate to the main routes of manganese exposure by human beings.

First is occupational exposure to airborne dust. Ingested Mn or dermal exposure are not concerns in an occupational setting. The next three deal with exposure by the general population. Mn is a ubiquitous metal in the environment and is commonly found in soils and groundwater. It is also present in many important foodstuffs and some dietary supplements and vitamins. Most environmental exposure to Mn is completely natural but airborne Mn levels can be elevated in close proximity to a Mn processing facility. Over the past 40 years, airborne Mn levels have dropped 80-90% in some highly industrialized areas.

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In the 1960's and 70's, as many of the metal and chemical industries experienced more stringent regulations, Mn was still lightly regulated. The standards were minimal and feasible to implement. Air, water and solid waste regulations were based on overall cleanliness and aesthetics rather than driven by health concerns. The occupational standard was set at 5 mg/m3 although very high exposure over a significant time period was known to induce the neurological syndrome called "Manganism" as well as some respiratory deficits. In many ways, Manganism, resembles the common illness, Parkinsons Disease, but is now know to be clinical different.

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Things began to change in the mid-1980's as epidemiological studies were published describing occupational settings with low exposures; much below the existing standards. These studies used new tests that looked for subtle changes in neurological system performance. Comparison of exposed and control group workers on tests such as tremor, eye-hand coordination, reaction time, etc. showed differences between the groups when using sophisticated statistics. For the first time, researchers reported finding subclinical adverse effects at what was considered low levels of exposure – less than 1 mg/m3. As there was no evidence of clinical manganism in the populations, industry questioned the use of these new non-validated testing protocols. However, with this evidence, the researches cited the need to be protective and pushed for lower exposure standards.

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In the early 1990's, the perception of Mn changed. The metal transformed from a relatively benign mineral into a chronic neurotoxin – one that could have negative effects as workers aged. Even though there is still no evidence of such, the superficial relationship of Manganism to Parkinsons Disease helped spur the notion that low, chronic exposure to manganese was a significant risk for development of serious neurological illnesses later in life. While the incidence of manganese induced disease is virtually unknown in the United States, momentum developed to lower Mn exposure standards.

The other important point is the developing idea that inhaled Mn is much more toxic than ingested Mn. As Mn is an essential element for human health, all humans process and circulate in the blood a level of Mn that is significant in the context of environmental exposures.

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In 1992, Industry saw the first direct impact when the ACGIH issued a Notice of Intended Change to lower the Threshold Limit Value (TLV) for occupational exposure to Mn from 5.0 mg/m3 to 0.2 mg/m3. As the TLV had largely been in place for over 45 years, this was a major change. Even though ACGIH is a private, advisory organization, it holds great influence both in the U.S. and in much of the world. In many countries, ACGIH standards are simply adopted as binding, national standards. Following adoption of the new standard in 1995, the ACGIH just recently announced its intention to lower the standard even further, to 0.03 milligram/m3, although the basis of the standard will be changed to respirable dust.

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While ACGIH is an advisory body, OSHA is the federal agency that issues binding regulations governing the workplace. In this regard, the existing Mn exposure standard is still 5 mg/m3 – the same value for many years. In 1996, OSHA announced a change in the Mn Permissible Exposure Limit but so far, there has been no proposed value. OSHA is currently consumed with other regulatory initiatives but we do expect to see a proposed standard in the next few years – one probably very similar to the ACGIH value.

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For any company in the metal or chemical business, the Environmental Protection Agency provides the most comprehensive oversight. Acting through the state agencies, federal laws are implemented thru a labyrinth of regulations governing many aspects of chemical storage, production, and emissions. Dealing with emissions only, EPA regulates air, water and solid waste discharges.

For air emissions, Mn is classified as a hazardous air pollutant under the Clean Air Act. All point sources are controlled using Best Available Control Technologies but a major source such as an ore processing or alloy plant would also be subject to a site wide permit that regulates all fugitive emission as well. Any process change that might increase site emissions would affect the entire site permit.

EPA has also developed a Reference Concentration value for Mn in ambient air. Reported as the safe level of Mn exposure for the general population, it was derived using a 300 fold safety factor to convert relevant occupational exposures to environmental exposures. At the current value of 0.05 microgram/m3, it is five orders of magnitude lower than the current OSHA occupational standard.

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Mn is a common constituent in most bodies of water due to natural weathering of rocks and soils. A permitted discharge limit considers the natural level of Mn in the body of water and then allows flexibility to meet the limit. Since Mn is also common in the food chain, the Reference or Safe Dose for Mn is a relatively high 10 milligrams of Mn per day. For drinking water, Mn is controlled at 40 parts per billion for reason of taste and staining. However, EPA is studying whether a health based standard should be instituted.

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Currently, Mn containing wastes are not considered hazardous and may be disposed of in industrial landfills. However, precautions must be taken to ensure that soluble Mn does not contaminate groundwater. In actuality, in order to

prevent future liability, most manganese wastes are stored in lined ponds and old ponds are capped with impermeable materials. In 2001, EPA proposed a rule that would have listed a waste from the titanium industry as “hazardous” partially due to the presence of Mn. This rule would have also added Mn to the list of substances that would be considered in any future ruling regarding listed hazardous waste. Fortunately, industry was able to prevail upon EPA to remove Mn from the listing.

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There are several other agencies of the U.S. Government that consider Mn exposure in the general population. The Agency for Toxic Substance Disease Registry looks at possible exposures due to proximity to industrial sources or waste dumps. Using a similar methodology as the EPA, ATSDR ruled that a Minimal Risk Level for airborne Mn is 0.04 microgram/m3 – nearly the same value as the EPA RfC.

The Food and Drug Administration has looked closely at the range of dietary exposures. Recognizing that Mn is an essential human trace element and that there is no evidence of adverse health effects due to dietary exposures, the FDA determined that a safe and adequate intake was 2-5 mg per day. FDA is concerned with dietary supplements that contain 20, 50 and even 100 mg of Mn but still there is little evidence that these supplements result in health problems.

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Represented by The Ferroalloys Association, a number of companies engaged in the production and use of Mn have developed positions based upon the best available science and have communicated with the relevant agencies. One of the key points is to remind the agencies that Mn is an essential element and should not be regulated as one that is foreign to the human body.

On the subject of a occupational exposure standard, industry believes that a value of 0.2 mg/m3 measured as respirable dust is fully protective. This is based on the most recent studies that show no adverse health effects at levels of 0.07 mg/m3 and that the subclinical effects discussed earlier are not materially significant.

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Industry does agree that air emission sources should be controlled using Best Available Control Technologies but that ambient air standards should not be set using huge and unrealistic safety factors. For drinking water and solid waste regulation, consideration must be made of all sources of Mn in the diet.

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In summary, the toxicity of Mn has not changed. There are no new highly toxic manganese compounds and no new pathologies to consider but the perception has changed dramatically. The Regulatory Environment that exists now is constantly pushing for lower exposures and lower exposure standards. Over the past 10 years, the manganese industry has become a credible and knowledgeable voice. While not always successful, industry has prevailed by supplying facts, data and a science based argument. Continued vigilance and involvement with the regulatory agencies will help ensure that future standards are both feasible and based on sound science.